

# Notice of Allowability

Application No.

10/022,115

Examiner

Joanne Hama, Ph.D.

Applicant(s)

SAWYERS ET AL.

Art Unit

1632

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/11/05.
2. ☒ The allowed claim(s) is/are 21-26 and 35.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

  
**Q. JANICE LI, M.D.**  
**PRIMARY EXAMINER**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Jean Lockyer on December 19, 2005. An additional telephone call with Ms. Lockyer on December 28, 2005 authorized a second set of claim amendments.

The Application has been amended as follows:

In claim 21, line 3, the phrase, "androgen-dependent" was inserted between "human" and "prostate".

In claim 21, line 6, the phrase, "growth of the" was inserted between "the" and "xenograft."

In claim 26, line 4, the word, "whether" was inserted in place of "that".

In claim 26, line 5, the phrase, "androgen-dependent" was inserted between "human" and "prostate".

The following is an examiner's statement of reasons for allowance:

The instant claims are drawn to a method for assessing the effect of a composition or treatment on human prostate cancer in a mouse model, comprising:

a) providing an immune deficient mouse comprising a human androgen-dependent prostate cancer xenograft of locally advanced or metastatic prostate cancer

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tissue or a cell suspension thereof, wherein the xenograft is allowed to grow for a sufficient time to permit the detection of a tumor or of metastatic prostate cancer cell, and wherein the growth of the xenograft simulates disease progression from androgen-dependence to androgen-independence,

- b) subjecting the mouse to the composition or treatment, and
- c) determining the effect of the composition or treatment on the growth of the xenograft in said mouse.

The closest art at the time of filing is Wu et al., 1994, Int. J. Cancer, 57: 406-412.

Wu et al. teach:

- a) Co-injection of a non-tumorigenic prostate cancer cell line (LNCaP) with a bone stromal cell line. LNCaP is not a metastatic cell line.
- b) There is no observation from androgen-dependence to androgen-independence in non-castrated nude mice.
- c) The androgen-dependence to androgen-independence of LNCaP results from the interaction of LNCaP with the bone stromal cell line.

Accordingly, the cited prior art of record fails to teach the claimed invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is (571) 272-2911. The examiner can normally be reached on Monday-Friday 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JH



**Q. JANICE LI, M.D.**  
**PRIMARY EXAMINER**